



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0464]

Draft Guidance for Industry and Food and Drug Administration Staff; the Content of Investigational Device Exemption and Premarket Approval Applications for Artificial Pancreas Device Systems; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled “Draft Guidance for Industry and FDA Staff: The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems.” This draft guidance document provides industry and the Agency staff with guidelines for developing premarket submissions for artificial pancreas device systems, in particular, the Control-to-Range (CTR) and Control-to-Target (CTT) device systems. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled “Draft Guidance for Industry and FDA Staff: The Content of Investigational Device Exemption

(IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems” to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Phil Desjardins,
Center for Devices and Radiological Health,
Food and Drug Administration,
10903 New Hampshire Ave.,
Bldg. 66, rm. 5452,
Silver Spring, MD 20993-0002,
301-796-5678.

SUPPLEMENTARY INFORMATION:

I. Background

Diabetes mellitus has reached epidemic proportions in the United States and more recently, worldwide. The morbidity and mortality associated with diabetes is anticipated to

account for a substantial proportion of health care expenditures. Although there are many devices available that help patients manage the disease, FDA recognizes the need for new and improved devices for treatment of diabetes. One of the more advanced diabetes management systems is an artificial pancreas device system. An artificial pancreas system is a type of autonomous system that adjusts insulin infusion based upon the continuous glucose monitor (CGM) via control algorithm. There are a variety of types of artificial pancreas systems depending upon the nature of the control algorithm, including CTR, CTT, and Low Glucose Suspend systems. On June 22, 2011 (76 FR 36542), FDA announced the availability of the draft guidance document entitled “Draft Guidance for Industry and Food and Drug Administration Staff: The Content of Investigational Device Exemption and Premarket Approval Applications for Low Glucose Suspend Device Systems.” In this notice, FDA is announcing a draft guidance document with recommendations developing premarket applications for other types of artificial pancreas systems.

CTR and CTT systems link a continuous glucose monitor to an insulin pump and automatically reduce or increase insulin infusion based upon specified thresholds of measured interstitial glucose levels. These types of systems are designed to aid in the management of diabetes. There are significant challenges in creating an autonomous system, which were discussed in a joint FDA and NIH (National Institutes of Health) artificial pancreas workshop on November 10, 2010 (information available at

<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm226251.htm>).

Currently, there is no FDA-approved artificial pancreas device. This workshop sought feedback on ways to overcome the obstacles toward developing an artificial pancreas. The feedback received from this workshop and the continued communication with investigators in this field

has provided valuable input for FDA's guidances for artificial pancreas device systems. This guidance will outline considerations for development of clinical studies, and recommends elements that should be included in IDE and PMA applications, focusing on critical elements of safety and effectiveness for approval of this device type.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on developing investigations of and premarket applications for Artificial Pancreas Device systems, particularly the CTT and CTR device systems. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive "Draft Guidance for Industry and FDA Staff: The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems," you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1786 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to currently approved collections of information found in FDA regulations and guidance documents. These collection of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 56.11 are approved under OMB control number 0910-0130; the collections of information in 21 CFR parts 801 and 809 are approved under OMB control number 0910-0485, the collections of information in 21 CFR part 812 are approved under OMB control number 0910-0078, and the collections of information in 21 CFR part 814 are approved under OMB control number 0910-0231; the collections of information in 21 CFR part 820 are approved under OMB control number 0910-0073.

V. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 28, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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